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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/647,752	08/26/2003	Richard F. Stockel		2291

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EXAMINER

ROBERTS, LEZAH

ART UNIT PAPER NUMBER

1614

DATE MAILED: 12/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/647,752	Applicant(s) STOCKEL, RICHARD F.	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) 2,5,6,9-11 and 13-20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,7,8 and 12 is/are rejected.
- 7) ☒ Claim(s) 12 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

- 1) a dentifrice compositions consisting of:
- 2) a biocidal complex: the biocidal complexes are made up of; a cationic monomeric or polymeric biocide and anionic monomeric biocide, and the other made up of a biocidal base and a biocidal acid; and
- 3) a surfactant.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1 and 2 are generic.

Applicant is required to select a dentifrice; a biocidal complex electing a cationic and anionic biocide, or a biocidal acid and base; a surfactant; and a composition electing each component of the composition (for example the specific agents in claim 12: the specific biocidal complex, the specific surfactant, ethanol and water. The election must be made with or without traverse. It is suggested to elect with traverse in order to maintain your rights to claims of a nonelected species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Richard Stockel on November 4, 2005 a provisional election was made with traverse to prosecute the invention of a mouthwash consisting of chlorhexidine-thymol complex as the biocidal complex, Tego Betaine ZF and ethanol; claims 1, 3, 4, 7, 8 and 12. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 5, 6, 9-11 and 13-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

(b) CROSS-REFERENCE TO RELATED APPLICATIONS.

(c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.

(d) THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT

(e) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or

REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a).

"Microfiche Appendices" were accepted by the Office until March 1, 2001.)

(f) BACKGROUND OF THE INVENTION.

(1) Field of the Invention.

(2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(g) BRIEF SUMMARY OF THE INVENTION.

(h) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).

(i) DETAILED DESCRIPTION OF THE INVENTION.

(j) CLAIM OR CLAIMS (commencing on a separate sheet).

(k) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).

(l) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

Claims

Examiner's Note

Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Claim Objections

Claim 12 is objected to because of the following informalities: the term "diocidal" is misspelled and should read "biocidal". Appropriate correction is required.

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 12 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim is indefinite insofar as the basis for the percent calculation is not set forth, e.g., percent by weight based on the total weight of the composition, percent by volume based on the volume of the carrier, etc. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that where a claimed value varies with its method of measurement and several alternative methods of measurement are available, the claimed value is indefinite unless the particular method of measurement is recited.) The percent calculation must either be clearly defined within the specification or set forth within the claim.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claims 1, 3, 4, 7, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Gaffer et al. (US 6,214,320).

Gaffer et al. teaches oral compositions containing anticalculus and antiplaque agents. The compositions can consist of several different components, some of which are recited in the instant claims. The invention includes a cationic antimicrobial agent (col. 3, lines 41-48), preferably chlorhexidine digluconate (col. 4, line 62) and the % weight ranges from at least 0.01% to about 5% (col. 7, lines 49-52). When compounds such as chlorhexidine are used, the preferred anticalculus agent is one which provides the 1-azacycloheptylidene-2-2-diphosphonate anion and may be in the acid form or suitable salt (col. 8, lines 54-58). Also included in the invention are surfactants such as cocoamidopropyl betaine (see example 1) from about 0.2 –3 % weight (col. 18, lines 14-26). The mouthwashes or rinses of the invention include ethanol water mixtures making up 70 to 99.9 % of the composition and the ratio ranges from about 1:1 to 20:1 water to alcohol (col. 12, lines 66-67 and col.13, lines 1-11). The reference anticipates the instant claims insofar as to disclose a mouthwash composition that comprises an anionic and cationic compound, which can form a complex; a betaine surfactant; ethanol and water.

2) Claims 1, 3, 4, 7, 8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Polefka et al. (US 5,180,577).

Polefka teaches oral compositions containing a cationic antibacterial agent, anionic active ingredient and a betaine surfactant as a stabilizing agent (see abstract).

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The cationic antibacterial agents are bis biguanide. The antibacterial bis biguanide of choice is the digluconate of chlorhexidine i.e. 1,1'-hexamethylene-bis-(4-chlorophenyl)-biguanide (col. 5, lines 46-48). Chlorhexidine was used in the amount of 0.12% in the mouthrinses (see example 1). There are several choices for the anionic active ingredient, for example anionic active agents may be provided to impart anticaries properties, antitartar or calculus properties, anti-staining properties or the like (col. 5, lines 54-58). The anionic compound was used in the amount of 0.50 % (see example 1). These include fluoride salts, ethylenediamine tetracetic acid, certain polyphosphates, soluble pyrophosphates and pyrophosphates (col. 6, lines 43-64). The inclusion of the betaine surfactant in the relatively narrow range of concentrations prescribed herein has been discovered to allow for effective employment of both the anionic agent and the cationic antimicrobial (col. 3, lines 28-31). The betaine used is Tego-betaine also known as cocoamidopropyl betaine in the amount of 0.25 % (see example 1). The compositions are brought to 100 % with water. The reference clearly anticipates the instant claims insofar as to disclose mouthwash composition comprising a cationic-anionic complex, betaine and water.

Claim Rejections - 35 USC § 103 - Obviousness

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 8 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Polefka et al. (US 5,180,577) in view of Sköld et al. (Eur J. or Oral Sci. 1998).

The primary reference is discussed above. The reference differs from the instant claims insofar as to not disclose the use of thymol to make the anionic-cationic complex.

Sköld et al. evaluates the effect on an antibacterial chlorhexidine/thymol containing varnish on gingival inflammation. It was concluded topical application of a chlorhexidine/thymol-containing antibacterial varnish results in a reduction of gingival inflammation and may thus be beneficial for patients with fixed orthodontic appliances. The reference differs from the instant claims insofar as not using the complex in a mouthrinse containing water, optionally ethanol and betaine.

It would have been obvious to one of ordinary skill in the art to have incorporated the chlorhexidine/thymol of the secondary reference into the mouthwash of the primary reference motivated by the desire to produce a mouthwash that could reduce

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inflammation caused by gingivitis and orthodontic appliances as well as act as an antibacterial mouthwash.

Examiner' Suggestion

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
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